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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,484	11/28/2001	Yen Choo	8325-2004 G8-US1	2713

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EXAMINER
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SULLIVAN, DANIEL M

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 05/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/996,484

**Applicant(s)**

CHOO ET AL.

**Examiner**

Daniel M. Sullivan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2005 and 21 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5,7,8,10,11,13-18,21-26,31,34,35 and 38-47 is/are pending in the application.
- 4a) Of the above claim(s) 1-5,7,8,10,11,13-18,21-26,31,35 and 38-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 18 January 2005 has been entered.

This Office Action is a reply to the Papers filed 18 January 2005 and 21 March 2005 in response to the Final Office Action mailed 17 November 2004. Claims 1-5, 7, 8, 10, 11, 13-18, 21-26, 31, 35 and 38-47 are withdrawn from consideration and claim 34 was considered in the 18 January Office Action. Claims 1, 14 and 34 were amended in the 18 January Paper. Claims 1-5, 7, 8, 10, 11, 13-18, 21-26, 31, 34, 35 and 38-47 are pending and claim 34 is under consideration.

### ***Response to Amendment and Arguments***

#### **Claim Rejections - 35 USC § 102**

Rejection of claim 34 under 35 U.S.C. 102(e) as being anticipated by any one of Crabtree *et al.* US Patent No. 6,046,047; Natesan *et al.* US Patent No. 6,479,653; Natesan US Patent No. 6,015,709; or Pomerantz *et al.* 6,326,166 is withdrawn in view of the amendment of the claim such that the first and second polypeptides of the switching system must bind DNA. This limitation is not found in the teachings of the cited art.

Claim 34 stands rejected under 35 U.S.C. 102(b) as being anticipated by McEwan *et al.* (1996) *BioEssays* 19: 153-160 for reasons of record and as evidenced by Bledsoe (2002) *Cell* 110: 93-105. Please note that Bledsoe is relied upon only to establish properties that are inherent to the switching system of McEwan *et al.*

In response to the *prima facie* rejection of record, Applicant has amended the claim such that both of the first or second polypeptides of the switching system must bind to DNA and the ligand binds to both of the first and second polypeptides. Applicant contends that the Office does not make clear which of the proteins disclosed in Table 1 of McEwan binds DNA. Applicant further suggests that the Office must identify a particular receptor-protein pair, and show that both members of the pair bind DNA and that McEwan fails to teach that any ligand binds both to its receptor and to a second DNA-binding protein.

Applicant's arguments have been fully considered but are not deemed persuasive. As pointed out in the Advisory Action mailed 8 February 2005, "the Final Office action states, 'McEwan *et al.* describes in detail the DNA binding domain comprised within the glucocorticoid, estrogen and retinoid receptor proteins comprised within the switching systems disclosed in Table 1' (page 3). Thus, the Office Action makes clear that at least the glucocorticoid, estrogen and retinoid receptor proteins of the complex bind DNA. This is further illustrated for the glucocorticoid receptor in Figure 4." Also illustrated in Figure 4 of McEwan *et al.* is the binding of the estrogen receptor to DNA as a homodimer, wherein both of the monomers of the receptor homodimer would be bound to ligand. Bledsoe *et al.* teaches, "[h]ormone binding initiates the release of chaperone proteins from the GR, allowing dimerization and translocation of the receptor into the nucleus" (second full paragraph in the

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right column on page 93). Thus, at least the glucocorticoid receptor switching system of McEwan *et al.* comprises a first and second polypeptide component which both bind to DNA and the ligand, wherein the first polypeptide binds to the second polypeptide in a manner modulatable by a ligand. Therefore, the teachings of McEwan *et al.* still anticipate the limitations of the instant claim 34.

### *New Grounds*

#### Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 34 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a new matter rejection.

The MPEP states, “[i]f new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. §112, first paragraph-written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981).” (MPEP § 2163.06). The MPEP further states, “[w]henever the issue arises, the fundamental factual inquire is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in

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the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in the application” (*Id.*, § 2163.02). The introduction of claim changes which involve narrowing the claims by introducing elements or limitations which are not supported by the as-filed disclosure is a violation of the written description requirement of 35 U.S.C. 112, first paragraph. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996).

As pointed out in the 8 February Advisory Action, the amendment to claim 34 introduces new limitations requiring that both the first and second polypeptides of the switching system bind to DNA and that the ligand binds to both polypeptides. Applicant cites page 53, line 18 of the specification in support of the limitation that the ligand binds to both polypeptide components of the complex. The passage cited reads, in full, as follows: “With regard to protein switches, the methods of the present invention typically involve using a tripartite configuration of one or more first polypeptide molecules, one or more ligands and one or more second polypeptide [sic] as described above to screen for (i) polypeptide binding molecules that bind to (another) target polypeptide in a manner that is modulatable by a ligand and/or (ii) ligands that modulate binding of two polypeptides to each other.” Nothing in this teaching would suggest that the protein switch be limited to those in which ligand binds to both polypeptide components.

According to MPEP §2163, “[t]o comply with the written description requirement of 35 U.S.C. 112, para. 1, or to be entitled to an earlier priority date or filing date under 35 U.S.C. 119, 120, or 365(c), each claim limitation must be expressly, implicitly, or inherently supported in the originally filed disclosure. When an explicit limitation in a claim ‘is not present in the

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written description whose benefit is sought it must be shown that a person of ordinary skill would have understood, at the time the patent application was filed, that the description requires that limitation.” (quoting *Hyatt v. Boone*, 146 F.3d 1348, 1353, 47 USPQ2d 1128, 1131 (Fed. Cir. 1998)). There is nothing in the statement cited by Applicant that would lead one of ordinary skill to understand that binding of ligand to both polypeptides is required by the switching system disclosed in the originally filed application. Therefore, the limitation constitutes impermissible new matter.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Thursday 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Daniel M. Sullivan, Ph.D.

Examiner

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